Protection of Human Subjects and Vertebrate Animals Used in Research

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Human Subjects

- All uses of human subjects must be approved **IN ADVANCE!**
- No retroactive approvals!
- No exceptions!

What procedures must be followed when using human subjects in research?

- Research involving human subjects is governed by 15 CFR Part 27, the Common Rule.
- NIST procedures are set forth in Administrative Manual Subchapter 14.01.

Research Involving Human Subjects

- Very Broad – all areas of research
  - Study of human behavior, reactions and thought processes
  - Study of human body, tissues, organs, cells, cell lines, DNA, etc.

What at NIST is covered by the Common Rule?

- All research “conducted or supported” by NIST
  - NIST Employees, contractors and funding recipients
  - Guest Researchers
  - Outside parties using NIST facilities
  - Shared facilities, e.g., CARB, JILA
  - CRADAs

“Protected Classes”

- Children, prisoners, pregnant women, fetuses, fetal tissue, and human in vitro fertilization
- Protocol and informed consent form must be approved by a qualified Institutional Review Board (IRB) with a federal-wide assurance from DHHS
- NIST IRB is not authorized to review research involving Protected Classes.

Exemptions - Procedure

- If the research does not involve a Protected Class, and fits within one of the exemption categories listed in 15 CFR 27.101(b), the Laboratory/OU Director documents that determination in a memo to the NIST IRB Chairperson with concurrence by NIST Counsel. (See Admin Manual Subchapter 14.01, App. A.)

Exemptions - Examples

- For Protected Classes, exemptions only permitted in limited circumstances for research involving children.
- Surveys, interviews and questionnaires, observations of public behavior are often exempt.
- Existing records/specimens when publicly available or not identifiable with a particular subject.

NIST IRB Review -When

- If the research
  - does not involve a Protected Class,
  - is determined not to be exempt, and
  - is to be conducted at NIST

NIST IRB Purposes

- Protect physical and psychological well-being of human subjects participating in research
- Ensure design and conduct of NIST research using human subjects does not contribute to risk to the subjects.
- Serve as safeguard to protect NIST from errors in ethical judgment

IRB Review of Research I

- "Expedited Review"
  - When research involves no more than minimal risk
  - When there are minor changes in previously approved research within one year
  - Done by IRB Chair, who may request that experts or and/or other IRB members review, as well.

IRB Review of Research II

- IRB Review
  - When expedited review not acceptable
  - Meeting convened
  - Majority of IRB present, including at least one member from non-scientific area
  - Majority vote rules
  - Provides feedback to PI, if necessary

Criteria for IRB Approval of Research

- Risks to subjects are minimized
- Risks to subjects are reasonable in relation to anticipated benefits
- Informed consent sought and documented
- Adequate provisions protecting privacy of subjects
- Adequate provisions maintaining confidentiality of data

IRB Process

- Memo from OU Director to IRB Chair summarizing human subjects research protocol, with full documentation and recommendations
- IRB Chair decides if expedited review acceptable, or if full IRB review necessary
- IRB consideration and vote
- IRB may request changes to protocol and informed consent documents
- IRB approval document goes through NIST Counsel to NIST Deputy Director for approval
- PI notified by IRB Chair
- Approval must be renewed annually (within 365 days)

IRB Membership

- All members appointed by NIST Director
- Broad range of expertise and experience
- At least one member not affiliated with NIST
- NIST Counsel and ATP Human and Animal Subjects Advisor designated as ex-officio members
- All Labs and ATP represented

Current IRB Membership

- Alan Cookson, EEEL (Chair)
- Joseph Antonucci, MSEL
- Connie Chang, ATP
- Howard Harary, MEL
- Mary Jackson, DA
- Lisa Karam, PL
- Mirta-Marie Keys, OD
- Walter Liggett, ITL
- Terry Lynch, TS
- Charles MacKay, NIH
- Catherine O'Connell, CSTL
- Cynthia Reed, BFRL
- Mike Rubin, NIST Counsel, (ex-officio)
- Melissa Lieberman, NIST Counsel, (ex-officio)
- Tryn Stimart, ATP, (ex-officio)

Investigator Responsibilities - I

- Primary responsibility for protecting rights and welfare of human subjects research
- Knowledgeable about Federal regulations, NIST policies and procedures for protection of human subjects
- Education requirements
- Conduct research according to IRB-approved protocol and IRB determinations

Investigator Responsibilities - II

- Ensure that each potential subject understands nature of research and their participation
- Provide and keep a copy of IRB-approved informed consent form to each subject

Investigator Responsibilities - III

- Promptly report proposed changes in activities to IRB - do not initiate until approved by IRB
- Report progress to IRB as prescribed
- Promptly report to IRB unanticipated problems involving risks to subjects and others

Informed Consent

- Basic Concepts of consent process include:
  - Full disclosure of nature of research and subject's participation
  - Adequate comprehension on part of potential subject
  - Subject's voluntary choice to participate
- Specific requirements for informed consent set forth in Common Rule (15 CFR 27.116) and NIST Admin Manual Subchapter 14.01, App.C

Consent Process

- Informed consent obtained prospectively from subject or legal representative
- Information in understandable language
- Subjects given opportunity to consider
- Consent must be given without coercion or undue influence
- Subjects must not give up legal rights or be given impression that they are being asked to do so

Elements of Informed Consent - I

- Federal regulations detail specific elements of information provided to each subject:
  - Description of research and subject's participation, incl. experimental procedures
  - Description of reasonably foreseeable risks
  - Description of expected benefits to the subject or others
  - Potentially advantageous alternatives to participation

Elements of Informed Consent - II

- Explanation of confidentiality protections
- Explanation of compensation for injuries policy
- Whom to contact with questions
- Explanation that participation is voluntary

NIST Institutional Review of NIST-Supported Research

- If the research
  - does not involve a Protected Class,
  - is determined not be exempt, and
  - is to be conducted outside NIST
- Protocol and informed consent form must be approved by a qualified external IRB
- Approved protocol, informed consent form, and external IRB approval documentation must be approved by the NIST Deputy Director

Contact

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Vertebrate Animals

- All uses of vertebrate animals must be approved **IN ADVANCE!**
- No retroactive approvals!
- No exceptions!

What procedures must be followed when using vertebrate animals in research?

- Research involving vertebrate animals is governed by the Animal Welfare Act (7 U.S.C. 2131 et seq.), FDA regulations (21 CFR Part 58), and guidance and policies set forth by DHHS.
- NIST procedures are set forth in Admin Manual Subchapter 14.02.

What is covered?

- Use of live vertebrate animals in research
- Housing of live vertebrate animals for research
- Does not cover animal tissues or cell lines

Research Involving Vertebrate Animals Conducted at NIST

- Before research involving vertebrate animals is conducted at NIST, or animals housed at NIST, the Animal Study Protocol (ASP) must be approved by the NIST Institutional Animal Care and Use Committee (IACUC).

Research Involving Vertebrate Animals Supported by NIST

- Before research involving vertebrate animals is supported by NIST,
  - ASP must be approved by the cognizant IACUC, and
  - ASP, IACUC accreditation, and IACUC approval of the ASP must be approved by the NIST IACUC Chairperson.

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